Docket No.

283523US0PCT

MAIL STOP PCT

IFW

# IN THE UNITED STATES PASENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Gian L ARALDI et al

SERIAL NO:

10/564,974

GAU:

FILED:

January 18, 2006

**EXAMINER:** 

FOR:

HYDRAZIDE DERIVATIVES AS PROSTAGLANDIN RECEPTORS MODULATORS

## **INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

#### REFERENCES

The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.

☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### RELATED CASES

Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.

A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

#### CERTIFICATION

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

□ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

#### **DEPOSIT ACCOUNT**

Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number <u>15-0030</u>. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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| Form PTO 1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE |            |   |                 | ATTY DOCKET NO.                               |                   | SERIAL NO.   |                                       |  |
|--|------------|---|-----------------|---|-------------------|--------------|---------------------------------------|--|
|  |            |   | 283523US0PCT    | 10/564,974                                    |                   |              |                                       |  |
|  |            |   | APPLICANT       |   |                   |              |                                       |  |
| LIST OF REFERENCES CITED APPLICANT  APR 1 8 7006                                 |            |   |                 | Gian L ARALDI, et al.                         |                   |              |                                       |  |
|  |            |   |                 | FILING DATE                                   |                   | GROUP        |                                       |  |
|  |            |   |                 | January 18, 2006                              |                   |              |                                       |  |
|  |            | 12  |                 | U.S. PATENT DOCUMENTS                         |                   |              |                                       |  |
| EXAMINER<br>INITIAL  |            | DOCUM <b>ENT</b><br>NUMBER  | TE TE           | NAME  | CLASS             | SUB<br>CLASS | FILING DATE<br>IF APPROPRIATE         |  |
|  | AA         | 6 235 780   | 05/22/01        | OHUCHIDA et al.                               |                   |              |                                       |  |
|  | AB         | 5 281 590   | 01/25/94        | HUSA et al.                                   |                   |              |                                       |  |
|  | AC         | 2001 0056060  | 12/27/01        | CAMERON et al.                                | i i               |              | · · · · · · · · · · · · · · · · · · · |  |
|  | AD         | 2002 0004495  | 01/10/02        | HARADA et al.                                 |                   |              |                                       |  |
| FOREIGN PATENT DOCUMENTS   |            |   |                 |   |                   |              |                                       |  |
|  |            | DOCUMENT DATE   |                 | COUNTRY                                       |                   | TRANSLATION  |                                       |  |
|  |            | NUMBER  | DATE            | 000,1111                                      | <del> </del>      | YES          | SNO                                   |  |
|  | ΑE         | 01 46140  | 06/28/01        | wo  |                   |              | NO                                    |  |
|  | AF         | 1 114 816   | 07/11/01        | EP  |                   | ***          | NO                                    |  |
|  | AG         | 99 33794  | 07/08/99        | wo  |                   |              | NO                                    |  |
|  | АН         | 02 42268  | 05/30/02        | wo  |                   |              | NO                                    |  |
|  | Al         | 99 02164  | 01/21/99        | wo  |                   |              | NO                                    |  |
|  | AJ         | 02 24647  | 03/28/02        | WO (with English abstract)                    |                   |              | NO                                    |  |
|  | AK         | 00 03980  | 01/27/00        | WO (with English abstract)                    |                   |              | NO                                    |  |
| •  | 1          | OTHER RE  | FERENCES (      | '<br>Including Author, Title, Date, Pertinent | Pages, e          | tc.)         | •                                     |  |
|  | AL         | ABRAMOVITZ et al. "The utilization of recombinant prostanoid receptors to determine the affinities and selectivities of prostaglandins and related analogs", Biochimica et Biophysica Acta, vol. 1483, pages 285-293 2000                               |                 |   |                   |              |                                       |  |
|  | AM         | BENOIT et al. "Latest discoveries in prostaglandin receptor modulators", Expert Opin. Ther. Patents, vol. 12, no. 8, pages 1225-1235 2002   |                 |   |                   |              |                                       |  |
|  | AN         | CHOUNG et al. "Role of EP2 Receptors and cAMP in Prostaglandin E2 Regulated Expression of Type I Collagen alpha1, Lysyl Oxidase, and Cyclooxygenase-1 Genes in Human Embryo Lung Fibroblasts", Journal of Cellular Biochemistry, vol. 71, pages 254-263 |                 |   |                   |              |                                       |  |
|  | AO         | 1998 COLEMAN et al. "Prostanoids and their Receptors", In Comprehensive Medicinal Chemistry, The rational Design, Machanistic Study and Therapeutic Application of Chemical Compounds, vol. 3, pages 643-714  |                 |   |                   |              |                                       |  |
|  | AP         | 1989 COLEMAN et al. "VIII. International Union of Pharmacology Classification of Prostanoid Receptors: Properties, Distribution, and Structure of the Receptors and Their Subtypes", Pharmacological Reviews, vol. 46, no. 2, pages 205-229             |                 |   |                   |              |                                       |  |
|  | AQ         | 1994  FLEISCH et al. "LY171883, 1-<2-Hydroxy-3-Propyl-4-<4-(1H-Tetrazol-5-yl) Butoxy>Phenyl>Ethanone, an Orally Active Leukotriene D4 Antagonist", Journal of Pharmacology and Experimental Therapeutics, vol. 233, no. 1, pages 148-157                |                 |   |                   |              |                                       |  |
|  | AR         | 1985 FORMICA et al. "Comparative Assessment of Bone Mineral Measurements Using Dual X-ray Absorptiometry and Peripheral Quantitative Computed Tomography", Osteoporos Int, vol. 8, pages 460-467  |                 |   |                   |              |                                       |  |
|  |            | 1998  |                 |   |                   |              |                                       |  |
|  | AS         | HYMAN et al. "Oral prostaglandin (PGE2) therapy for chronic viral hepatitis B and C", Journal of Viral Hepatitis, vol. 6, pages 329-336 1999  |                 |   |                   |              |                                       |  |
|  | АТ         | MELTZER et al. "Substituted 3-Phenyltropane Analogs of Cocaine: Synthesis, Inhibition of Binding at Cocaine Recognition Sites, and Positron Emission Tomography Imaging", J. Med. Chem., vol. 36, pages 855-862 1993                                    |                 |   |                   |              |                                       |  |
|  | AU         | MIYAURA. "Role of EP4 receptor in bone resorption induced by PGE", Folia Pharmacol. Jpn., vol. 117, pages 293-297 with partial English translation 2001   |                 |   |                   |              |                                       |  |
|  | AV         | DE MICO et al. J. Org.<br>1997  | Chem., vol. 6   | 2, pages 6974-6977                            | Addi              | tional Refe  | rences sheet(s) attached              |  |
| Examiner   |            |   |                 |   | Date Cor          | nsidered     |                                       |  |
| *Examiner: In  | itial if r | eference is considered  | whether or not  | t citation is in conformance with MPEP 60     | l<br>)9: Draw lii | ne through   | citation if not in                    |  |
| conformance  | and no     | ot considered. Include co   | py of this form | with next communication to applicant.         | , DIGW III        | .5 anough    | J. 333011 11 1101 111                 |  |

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| (Modified)   | PATENT AND TRADEMARK OFFICE   | 283523US0PCT                              | 10/564,974                                 |  |  |  |  |
| OIP  | F   | APPLICANT                                 |  |  |  |  |  |
| LIST OF REFE   | RENCES CITED BY APPLICANT   | Gian L ARALDI, et al.                     |  |  |  |  |  |
| APR 18   |   | FILING DATE                               | GROUP                                      |  |  |  |  |
| \ <b>3</b>   |   | January 18, 2006                          |  |  |  |  |  |
| OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)  |   |   |  |  |  |  |  |
| AW   | LEVI et al. "Regulation of Prostanoid synthesis in microglial cells and effects of prostaglandin E2 on microglial functions", Biochemie, vol. 80, pages 899-904 1998                        |   |  |  |  |  |  |
| AX   | GAO et al. "Catalytic Asymmetric Epoxidation and Kinetic Resolution: Modified Procedures Including in Situ Derivatization", J. Am. Chem. Soc., vol. 109, pages 5765-5780 1987               |   |  |  |  |  |  |
| AY   | KATSUKI et al. "Synthesis of Saccharides and Related Polyhydroxylated Natural Products. 2. Simple Deoxyalditols", J. Org. Chem., vol. 47, pages 1378-1380 1982                              |   |  |  |  |  |  |
| AZ   | TAKAYAMA et al. "Prostaglandin E2 Suppresses Chemokine Production in Human Macrophages through the EP4 Receptor", Journal of Biological Chemistry, vol. 277, no. 46, pages 44147-44154 2002 |   |  |  |  |  |  |
| ААА  | TSUGENO et al. "Vertebral Fracture and Cortical Bone Changes in Corticosteroid-Induced Osteoporosis", Osteoporos Int, vol. 13, pages 650-656 2002   |   |  |  |  |  |  |
| ААВ  |   | ds Revealed From Studies Using Mice Lacki | ng Specific Prostanoid Receptors", Jpn. J. |  |  |  |  |
| AAC  |   |   |  |  |  |  |  |
| AAD  |   |   |  |  |  |  |  |
| AAE  |   |   |  |  |  |  |  |
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| ААМ  |   |   |  |  |  |  |  |
| Examiner   |   | D   | ate Considered .                           |  |  |  |  |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |   |   |  |  |  |  |  |

U.S. PCT Application Serial No: 10/564,974

Filed: January 18, 2006 Gian L ARALDI, et al.

Docket No. 283523US0PCT

### STATEMENT OF RELEVANCY

- 1) References AA, AB, AE have been cited in the International Search Report. A copy of these references is being submitted herewith.
- 2) References have been cited in the corresponding Search Report. A copy of these references is being submitted herewith.
- 3) References AC, AD, AF-AAB are discussed in the specification. A copy of these references is being submitted herewith.
- 4) References are additional prior art known to Applicant. A copy of these references is being submitted herewith.